

### **SUMMARY OF EXPRESS TERMS**

This regulation will amend Subpart 66-1 (School Immunization Requirements) to conform to recent amendments to Sections 2164 and 2168 of the Public Health Law (PHL). In addition, these amendments make the regulations consistent with national immunization recommendations and guidelines. The regulations also define the phrase “may be detrimental to the child’s health” for purposes of medical exemptions to vaccination requirements. The regulations will be effective upon publication of a Notice of Adoption in the New York State Register.

Technical amendments throughout Section 66-1.1 update references to the “Advisory Committee on Immunization Practices” (ACIP) schedule to its current title, the “Advisory Committee on Immunization Practices Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger.” Technical amendments also clarify the grades covered by the varicella, poliomyelitis and vaccine interval requirements.

Amendments to subdivision (g) of section 66-1.1 clarify that positive serologic tests for all three serotypes of poliomyelitis performed prior to September 1, 2019 may be accepted as evidence of poliomyelitis immunity. However, serologic tests against poliomyelitis performed on or after September 1, 2019 may not be accepted in place of poliomyelitis vaccination, in accordance with current ACIP guidance. Similar amendments are made to section 66-1.6 to incorporate these changes into the certificate of immunization.

A new subdivision (k) of section 66-1.1 adds a definition of laboratory confirmation of measles, mumps, rubella and varicella infections, and amendments to subdivision (g) of that section expand the definition of immunity to include laboratory confirmation against these diseases. Laboratory confirmation of immunity means a positive culture or polymerase chain reaction test against measles, mumps, rubella or varicella, or a positive blood test for Immunoglobulin M against measles or rubella, where such positive laboratory test is not otherwise explained by recent vaccination. Amendments to section 66-1.6 add laboratory confirmation of measles, mumps, rubella and varicella to the certificate of immunization.

A new subdivision (l) of section 66-1.1 defines “may be detrimental to the child’s health” to mean that a physician has determined that a child has a medical contraindication or precaution to a specific immunization consistent with ACIP guidance. Amendments to subparagraph (ii) of paragraph (4) of subdivision (c) of section 66-1.2 require that the reason why an immunization is detrimental to a child’s health be documented in the New York State Immunization Information System. Additionally, amendments to subdivision (c) of section 66-1.3 require the use of medical exemption forms approved by the New York State Department of Health or New York City Department of Education; a written statement from a physician is no longer allowed.

Finally, subdivision (d) of section 66-1.3 is repealed, and amendments to section 66-1.10 remove references to subdivision (d) of section 66-1.3.

Pursuant to the authority vested in the Commissioner of Health by sections 2164(10) and 2168(13) of the Public Health Law (PHL), sections 66-1.1, 66-1.2, 66-1.3, 66-1.6, and 66-1.10 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York are hereby amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Subdivisions (f), (g), (h), (i), and (j) of section 66-1.1 are amended, and new subdivisions (k), (l) and (m) are added, to read as follows:

- (f) *Fully immunized* means that an adequate dosage and number of doses of an immunizing agent licensed by the United States Food and Drug Administration has been received commensurate with the child's age, or the child has been demonstrated to have immunity as defined in this section.
- (1) For those immunizations required by section 2164 of the Public Health Law only, the number of doses that a child shall have at any given age, and the minimum intervals between these doses, shall be in accordance with the Advisory Committee on Immunization Practices Recommended Child and Adolescent Immunization [Schedules] Schedule for [Persons Aged 0 through] ages 18 [Years] years or younger, issued by the Advisory Committee on Immunization Practices (ACIP) as [set forth in *Morbidity and Mortality Weekly Reports* (MMWR) February 5, 2016 Volume 65 (No. 4)] referenced in Chapter 35 of the Laws of 2019 and posted on the Centers for Disease Control and Prevention website [at <http://www.cdc.gov/vaccines/schedules>. The department will amend this section as necessary to reflect revised ACIP Recommended Immunization

Schedules]. Any child who completed an immunization series following minimum intervals prescribed in an ACIP Recommended Immunization Schedule pre-dating February [2016] 2019 shall continue to be deemed in compliance as long as the number of vaccine doses the child received conforms to the current ACIP Recommended Immunization Schedule. [The Advisory Committee on Immunization Practices Recommended Immunization Schedules for Persons Aged 0 through 18 Years issued by the ACIP as set forth in the MMWR February 5, 2016 Volume 65 (No. 4) is hereby incorporated by reference, with the same force and effect as if fully set forth at length herein. It is available for public inspection and copying at the Regulatory Affairs Unit, New York State Department of Health, Corning Tower, Empire State Plaza, Albany, New York 12237. Copies are also available from the United States Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), Atlanta, Georgia 30333, and from the CDC website at [http://www.cdc.gov/vaccines/schedules/.](http://www.cdc.gov/vaccines/schedules/)]

- (i) For all vaccinations, except as provided in subparagraphs (ii) through (vii) [below] of this paragraph, children shall be assessed upon school entry or attendance, and annually thereafter, and be fully immunized commensurate with their age.
- (ii) Any child who has satisfied the immunization requirements in effect in regulation on June 30, 2014, entering [ninth through] twelfth grade (or comparable age level grade equivalents) in the [2016-2017] 2019-2020 school year only, shall be deemed in compliance with the immunization

requirements set forth in this section, including those set forth in subparagraphs (iii) through (vi) [below] of this paragraph, until such child graduates from school; provided, however, that such child shall comply with the meningococcal vaccination requirement set forth in subparagraph (vii) [below] of this paragraph.

- (iii) Any child entering or attending kindergarten through twelfth grade must have received the following vaccine doses, with the minimum intervals between these doses as established by the Advisory Committee on Immunization Practices Recommended Child and Adolescent Immunization [Schedules] Schedule for [Persons Aged 0 through] ages 18 [Years incorporated by reference herein] years or younger:
  - (a) Two adequate doses of measles containing vaccine, two adequate doses of mumps containing vaccine, and at least one adequate dose of rubella containing vaccine; and
  - (b) Five adequate doses of diphtheria and tetanus toxoids and acellular pertussis vaccine. If, however, the fourth dose of diphtheria and tetanus toxoids and acellular pertussis vaccine was given at [forty-eight] 48 months of age or older, only four adequate doses of vaccine are required. The final dose of vaccine must be received no sooner than [forty-eight] 48 months of age. Doses given after age seven should start with one dose of Tdap.
- (iv) [For poliomyelitis vaccination, beginning on or after July 1, 2014, children shall be assessed upon entry or attendance to kindergarten and sixth grade,

and/or their equivalent grades, and must have received four] Four adequate doses of poliomyelitis vaccine. If, however, the third adequate dose of poliomyelitis vaccine was given at [forty-eight] 48 months of age or older, only three adequate doses of vaccine are required. The final dose of vaccine must be received no sooner than [forty-eight] 48 months of age. [As the students enrolling in kindergarten and sixth grade move up a grade level each year, the students enrolling in those higher grades, or grade equivalent, must be appropriately immunized against poliomyelitis.] Beginning on or after September 1, 2016, children shall be assessed upon entry or attendance to child-caring centers, day-care agencies, nursery schools and pre-kindergarten programs and must be fully immunized against poliomyelitis commensurate with their age.

- (v) [For varicella vaccination, beginning on and after July 1, 2014, children shall be assessed upon entry or attendance to kindergarten and sixth grade, and/or their equivalent grades, and must have received two] Two adequate doses of varicella vaccine. [As the students enrolling in kindergarten and sixth grade move up a grade level each year, the students enrolling in those higher grades, or grade equivalent, must be appropriately immunized against varicella.]
- (vi) By entry to sixth grade or a comparable age level grade equivalent, any child [eleven] 11 years of age or older must have received one dose of a booster immunization containing tetanus and diphtheria toxoids and acellular pertussis vaccine.

(vii) For meningococcal vaccination, beginning on and after September 1, 2016, children shall be assessed upon entry or attendance to seventh grade, or a comparable age level grade equivalent, and must have received one adequate dose of vaccine upon such entry or attendance. Children shall be assessed upon entry or attendance to twelfth grade, or a comparable age level grade, and must have received two adequate doses of meningococcal vaccine upon such entry or attendance. If, however, the first dose of meningococcal vaccine was given at [sixteen] 16 years of age or older, then only one adequate dose of meningococcal vaccine is required for twelfth grade.

(2) If a child is not fully immunized, catch-up immunization must then take place according to the Advisory Committee on Immunization Practices Recommended Child and Adolescent Immunization [Schedules] Schedule for [Persons Aged 0 through] ages 18 [Years incorporated by reference in this subdivision] years or younger.

(g) *Immunity* means that:

(1) for measles, mumps, and rubella, [hepatitis B, and all three serotypes of poliomyelitis found in the polio vaccines,] a child has had a positive serologic test, as defined in subdivision (h) of this section [66-1.1(h)], for those diseases, or laboratory confirmation of disease, as defined in subdivision (k) of this section;  
[or]

- (2) for varicella, a child has either had a positive serologic test, as defined in subdivision (h) of this section [66-1.1(h),]; laboratory confirmation of disease, as defined in subdivision (k) of this section; or had the disease as verified by a physician, nurse practitioner, or physician's assistant statement[.];
  - (3) for hepatitis B, a child has had a positive serologic test, as defined in subdivision (h) of this section; or
  - (4) for poliomyelitis, positive serologic tests, as defined in subdivision (h) of this section, for all three serotypes of poliomyelitis, performed prior to September 1, 2019. Serologic tests against poliomyelitis performed on or after September 1, 2019 will not be accepted in place of poliomyelitis vaccination.
- (h) *Serologic test* means a positive blood test for Immunoglobulin G (IgG) or for hepatitis B, a blood test for hepatitis B surface antibody, as determined by the testing lab's criteria. Serology results reported as equivocal are not acceptable proof of immunity. A positive serologic test can be accepted in place of vaccination only for the following diseases: measles, mumps, rubella, varicella, hepatitis B and all three serotypes of poliomyelitis found in the polio vaccines.
- (i) [*Grace period*] *Age appropriate* means that vaccine doses administered within [4] four calendar days of the recommended minimum age or interval will be considered valid.
- (j) *In process* means that:

- (1) a child has received at least the first dose in each immunization series required by section 2164 of the Public Health Law (except in the case of live vaccines in which a child should wait 28 days after one live vaccine administration before receiving another live vaccine, if the vaccines were not given on the same day) and has age appropriate appointments to complete the immunization series according to the Advisory Committee on Immunization Practices Recommended Child and Adolescent Immunization [Schedules] Schedule for [Persons Aged 0 through] ages 18 [Years incorporated by reference at subdivision (f) of this section] years or younger; or
- (2) a child [is obtaining serologic tests] has had blood drawn for a serologic test and is awaiting test results within [30] 14 days [of notification of the parent/guardian that such testing is requested] after the blood draw; or
- (3) a child's serologic test(s) are negative, and therefore the child in question has appointments to be immunized within 30 days of notification of the parent/guardian to complete, or begin completion, of the immunization series based on the Advisory Committee on Immunization Practices Recommended Child and Adolescent Immunization [Schedules] Schedule for [Persons Aged 0 through] ages 18 [Years incorporated by reference at subdivision (f) of this section] years or younger.
- (4) Children who are not fully immunized can only continue to attend school if they are in the process of completing the immunization series based on the Advisory Committee on Immunization Practices Recommended Child and Adolescent Immunization [Schedules] Schedule for [Persons Aged 0 through] ages 18 [Years

incorporated by reference at subdivision (f) of this section] years or younger. If a child does not receive subsequent doses of vaccine in an immunization series according to the age appropriate ACIP catch-up schedule, including at appropriate intervals, the child is no longer in process and must be excluded from school within 14 days after the minimum interval identified by the ACIP catch-up schedule, if not otherwise exempt in accordance with section 66-1.3 of this Subpart.

(k) *Laboratory confirmation of disease* means, for measles, mumps, rubella or varicella, a positive laboratory test, either culture or polymerase chain reaction, detecting either the virus or viral-specific nucleic acid in a clinical specimen from the child or, for measles or rubella, a positive blood test for Immunoglobulin M (IgM) where such positive laboratory test is not otherwise explained by recent vaccination.

(l) *May be detrimental to the child's health* means that a physician has determined that a child has a medical contraindication or precaution to a specific immunization consistent with ACIP guidance or other nationally recognized evidence-based standard of care.

(m) *Attend or admit* means enrolled in, or admitted to, a school for the purpose of participating in or receiving services at such school, including but not limited to special education or related services, participating in intra-scholastic or interscholastic sports, or other school-sponsored events or activities; or being transported on a school bus or

vehicle with other school children; except where such services, transportation, events, or activities are open to the general public.

Subparagraph (ii) of paragraph (4) of subdivision (c) of section 66-1.2 is hereby amended to read as follows:

- (ii) For individuals exempt from administration of vaccines, providers must submit patient information, including the reason [for the exemption] that such immunization may be detrimental to the child's health, as defined in subdivision (l) of section 66-1.1 of this Subpart, to the statewide immunization information system within 14 days following the in-person clinical interaction that occurs at or after what would normally have been the due date for administration of an age-appropriate immunization to that child, according to current national immunization recommendations.

Subdivision (c) of section 66-1.3 is hereby amended to read as follows:

- (c) A signed, completed [sample] medical exemption form [issued] approved by the NYSDOH or [NYCDOHMH or a signed statement] NYC Department of Education from a physician licensed to practice medicine in New York State certifying that immunization may be detrimental to the child's health, containing sufficient information to identify a medical contraindication to a specific immunization and specifying the length of time the immunization is medically contraindicated. The medical exemption must be reissued annually. The principal or person in charge of the school may require additional information supporting the exemption.

Subdivision (d) of section 66-1.3 is repealed.

Section 66-1.6 is hereby amended to read as follows:

The certificate of immunization required in section 66-1.3(a) of this Subpart shall be prepared and signed by a health practitioner licensed in New York State and shall specify the products administered and the dates of administration. It may also show physician, nurse practitioner, or physician assistant-verified history of varicella disease and/or [laboratory evidence of immunity to] positive serologic tests for measles, mumps, rubella, varicella, and/or Hepatitis B [and all 3 serotypes of poliomyelitis contained in the polio vaccines] and/or laboratory confirmation of disease for measles, mumps, rubella and/or varicella. Certificates of immunization issued prior to September 1, 2019 may also show positive serologic tests for all 3 serotypes of poliomyelitis contained in the polio vaccines. A record issued by NYSIIS, the CIR, an official immunization registry from another state, an electronic health record, and/or an official record from a foreign nation may be accepted as a certificate of immunization without a health practitioner's signature.

Section 66-1.10 is hereby amended to read as follows:

- (a) For those diseases listed in PHL [§] section 2164 only, in the event of an outbreak, as defined in section 2.2(d) of this Title, of a vaccine-preventable disease in a school, the commissioner, or his or her designee, or in the City of New York, the Commissioner of Health of the New York City Department of Health and Mental Hygiene, may order the appropriate school officials to exclude from attendance all students who either have been exempted from immunization under section 66-1.3(c) [or (d)] of this Subpart, or are in

the process of receiving required immunizations pursuant to section 66-1.3(b) of this Subpart.

- (b) The exclusion shall continue until the commissioner or his or her designee, or in the City of New York, the Commissioner of Health of the New York City Department of Health and Mental Hygiene, determines that the danger of transmission has passed.
- (c) Schools must maintain a list of susceptible students who should be excluded from attendance in the event of an outbreak of vaccine preventable disease. This list must include all students who have been excused from immunization under section 66-1.3(c) [or (d)] of this Subpart and students who are in the process of completing immunization series or awaiting the results of serologic testing for any vaccine preventable disease specified under section 66-1.3(b) of this Subpart. The list shall be updated each time a new student enrolls in the school or a student's immunization status changes.

## **Regulatory Impact Statement**

### **Statutory Authority:**

The Commissioner of Health is authorized pursuant to Section 2164(10) of the Public Health Law (PHL) to adopt and amend rules and regulations necessary to effectuate the provisions and purposes of Section 2164 of the PHL. The Commissioner of Health is authorized pursuant to Section 2168(13) of the PHL to adopt and amend rules and regulations necessary to effectuate the provisions of Section 2168 of the PHL.

### **Legislative Objectives:**

The legislative objective of PHL § 2164 includes the protection of the health of residents of the state by assuring that children are immunized according to current recommendations before attending day care, pre-kindergarten, or school, to prevent the transmission of vaccine preventable disease and accompanying morbidity and mortality. The legislative objective of PHL § 2168 is to establish a comprehensive database of complete, accurate and secure immunization records.

Chapter 35 of the Laws of 2019 amended both PHL §§ 2164 and 2168, repealing the exemption from vaccination requirements for children whose parents had non-medical objections to immunizations.

### **Needs and Benefits:**

There currently exist outbreaks of measles in New York City and in the Counties of Rockland, Orange, and Westchester, and cases have also been identified in the County of

Sullivan. Measles is a viral disease transmitted via the airborne route when a person with measles coughs or sneezes. It is one of the most contagious diseases known. Following exposure to the virus about 90% of people who are susceptible will develop measles.

Measles can be a very serious disease. This is especially true for children less than 5 years of age, adults who are over 20 years of age, pregnant women and those who are immunocompromised. Common complications include ear infection and diarrhea. Severe complications include pneumonia and encephalitis. About one child out of 1,000 will get encephalitis, which can result in seizures. Deafness and other complications can occur. For every 1,000 cases of measles, one or two children will die, despite the best medical care. Measles can also cause premature birth in pregnant women.

The measles vaccine is very effective and remains the best protection against the disease. One dose of measles vaccine is about 93% effective at preventing the measles if exposed to the virus. Two doses are about 97% effective. The measles vaccine is also safe and serious side effects are rare.

According to the Centers for Disease Control (CDC), sustaining a high vaccination rate among school children is vital to the prevention of disease outbreaks, including the reestablishment of diseases that have been largely eradicated in the United States, such as measles. According to State data from 2017-2018, there are at least 280 schools in New York with an immunization rate below 85%, including 211 schools below 70%, far below the CDC's goal of at least a 95% vaccination rate to maintain herd immunity.

Endemic measles transmission had been eliminated in the United States. However, because some individuals have chosen not to receive the vaccine and to not have their children

vaccinated, outbreaks stemming from imported cases have occurred and new cases continue to occur in multiple counties across New York State.

In response to the current measles outbreak, the Legislature enacted Chapter 35 of the Laws of 2019, which repealed non-medical exemptions to the vaccination requirements for admission to day care, pre-kindergarten, or school. By increasing the number of children immunized against vaccine-preventable diseases like measles, this legislation will prevent outbreaks and protect both the immunized children and those members of the community who cannot be vaccinated for medical reasons.

This regulation conforms existing regulations with the provisions Chapter 35 of the Laws of 2019, by eliminating any reference to non-medical exemptions to vaccination rules for school admissions.

In addition, this regulation clarifies that a child may only receive a medical exemption from vaccination requirements when there is a medical contraindication or precaution to a specific immunization consistent with ACIP guidance. The regulation further requires that such contraindication be documented on forms approved by the Department of Health (Department) or the New York City Department of Education, and that they be documented in the New York State Immunization Information System. Although most physicians act in good faith and only issue medical exemptions for true medical contraindications to vaccination, as demonstrated by the experience of California, a small number may issue medical exemptions for non-medical reasons. In 2015, the State of California removed non-medical exemptions to school immunization requirements without taking steps to strengthen the rules governing medical exemptions. Over the next three years, the use of medical exemptions to school immunization

requirements more than tripled. By providing clear, evidence-based guidance to physicians, this regulation will help prevent medical exemptions being issued for non-medical reasons.

Finally, this regulation makes several technical amendments to conform with current guidance from the CDC's Advisory Committee on Immunization Practices (ACIP), including clarifying the grades covered by varicella, poliomyelitis and vaccine interval requirements; removing poliovirus from the list of diseases for which a positive serologic test is acceptable proof of immunity; and permitting laboratory confirmation of immunity to measles, mumps, rubella and varicella infections.

**Costs:**

**Costs to the Regulated Entity:**

Chapter 35 of the Laws of 2019 eliminates non-medical exemptions to school vaccination requirements. This created additional administrative work for the schools and day care businesses that are regulated under PHL § 2164. This regulation implements the law but does not impose any additional costs. Regulated entities that were already in compliance with the law will not have significant additional costs.

**Costs to Local Government:**

This regulation will affect schools, many of which are operated by local governments. The costs are as described above.

**Costs to the Department of Health:**

The Department intends to implement Chapter 35 of the Laws of 2019 and this regulation within existing appropriations.

**Local Government Mandates:**

Schools must already comply with Chapter 35 of the Laws of 2019.

**Paperwork:**

Children who previously had non-medical exemptions to school vaccination requirements will now have to provide regulated entities with evidence of immunity or a medical exemption. Regulated entities will need to maintain new paperwork for students who previously had religious exemptions.

**Duplication:**

These amendments do not duplicate, overlap or conflict with any Federal and State laws.

**Alternatives:**

An alternative would be not to amend the regulation to align with the Public Health Law as enacted by the Legislature. This alternative was rejected as unacceptable and inconsistent with the Department's duty to execute and implement the laws of New York State.

**Federal Standards:**

The Centers for Disease Control and Prevention maintains immunization schedules and guidelines for when immunization may be detrimental to a child's health because a child has a medical contraindication or precaution to a specific immunization.

**Compliance Schedule:**

There is no compliance schedule imposed by these amendments, which shall be effective upon publication of a Notice of Adoption in the New York State Register.

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## **Regulatory Flexibility Analysis for Small Businesses and Local Governments**

### **Effect of Rule:**

This regulation will apply to private schools, including parochial schools, and day care, some of which may be small businesses, as well as public schools operated by local governments. These regulated entities will be required to change their policies and procedures for school attendance to comply with PHL § 2164 and these regulations.

This regulation will also apply to physicians who may also be considered small businesses. In order to reduce the risk of medical exemptions being issued for non-medical reasons, physicians will be required to document the reason for granting medical exemptions in the New York State Immunization Information Systems (NYSIIS) and use medical exemption forms approved by the Department or the New York City Department of Education.

### **Compliance Requirements:**

All day care, pre-kindergarten, private and public schools must already comply with the requirements of Chapter 35 of the Laws of 2019. All physicians providing medical exemptions must comply with the requirement to document such exemptions as described above.

### **Professional Services:**

There are no additional professional services required as a result of this regulation.

### **Compliance Costs:**

Chapter 35 of the Laws of 2019 eliminated the non-medical exemption to school vaccination requirements. This created additional administrative work for the schools and day

care businesses that are regulated under PHL § 2164. This regulation implements the law but does not impose any additional costs. Regulated entities that were already in compliance with the law will not have significant additional costs. Physicians will not incur any additional costs.

**Economic and Technological Feasibility:**

This proposal is economically and technically feasible, as it does not require any special technology and does not impose an unreasonable financial burden on private schools, day care centers, public schools, or physicians.

**Minimizing Adverse Impact:**

The Department will work with regulated entities to ensure that they are aware of the requirements and have the information necessary to comply.

**Small Business and Local Government Participation:**

Small business, local government, and the public are invited to comment during the Codes and Regulations Committee meeting of the Public Health and Health Planning Council.

**Cure Period:**

Chapter 524 of the Laws of 2011 requires agencies to include a “cure period” or other opportunity for ameliorative action to prevent the imposition of penalties on a party subject to enforcement when developing a regulation or explain in the Regulatory Flexibility Analysis why one is not included. As this proposed regulation does not create a new penalty or sanction, no cure period is necessary.

## RURAL AREA FLEXIBILITY ANALYSIS

### Types and Estimated Numbers of Rural Areas:

This rule applies uniformly throughout the state, including in rural areas. Rural areas are defined as counties with a population less than 200,000 and counties with a population of 200,000 or greater that have towns with population densities of 150 persons or fewer per square mile. The following 43 counties have a population of less than 200,000 based upon the United States Census estimated county populations for 2010 (<http://quickfacts.census.gov>).

Allegany County	Greene County	Schoharie County
Cattaraugus County	Hamilton County	Schuyler County
Cayuga County	Herkimer County	Seneca County
Chautauqua County	Jefferson County	St. Lawrence County
Chemung County	Lewis County	Steuben County
Chenango County	Livingston County	Sullivan County
Clinton County	Madison County	Tioga County
Columbia County	Montgomery County	Tompkins County
Cortland County	Ontario County	Ulster County
Delaware County	Orleans County	Warren County
Essex County	Oswego County	Washington County
Franklin County	Otsego County	Wayne County
Fulton County	Putnam County	Wyoming County
Genesee County	Rensselaer County	Yates County
	Schenectady County	

The following counties have a population of 200,000 or greater and towns with population densities of 150 persons or fewer per square mile. Data is based upon the United States Census estimated county populations for 2010.

Albany County	Monroe County	Orange County
Broome County	Niagara County	Saratoga County
Dutchess County	Oneida County	Suffolk County
Erie County	Onondaga County	

This regulation will apply all day care, pre-kindergarten, and private and public schools, including parochial schools, as well as all physicians, throughout New York, including in rural areas.

**Reporting, Recordkeeping and Other Compliance Requirements; and Professional Services:**

This regulation will apply to public schools and private schools, including parochial schools, and day care in rural areas. These regulated entities will be required to change their policies and procedures for school attendance to comply with PHL § 2164 and these regulations.

This regulation will also apply to physicians in rural areas. In order to reduce the risk of medical exemptions being issued for non-medical reasons, physicians will be required to document the reason for granting medical exemptions in the New York State Immunization Information Systems (NYSIIS) and use medical exemption forms issued by the Department or the New York City Department of Education.

There are no additional professional services required as a result of this regulation.

**Costs:**

Chapter 35 of the Laws of 2019 eliminated the non-medical exemption to school vaccination requirements. This created additional administrative work for the schools and day care businesses that are regulated under PHL § 2164. This regulation implements the law but does not impose any additional costs. Regulated entities that were already in compliance with the law will not have significant additional costs. Physicians will not incur any additional costs.

**Minimizing Adverse Impact:**

The Department will work with regulated entities in rural areas to ensure that they are aware of the requirements and have the information necessary to comply.

**Rural Area Participation:**

Small business, local government, and the public are invited to comment during the Codes and Regulations Committee meeting of the Public Health and Health Planning Council.

### **JOB IMPACT STATEMENT**

No Job Impact Statement is required pursuant to Section 201-a(2)(a) of the State Administrative Procedure Act (SAPA). It is apparent, from the nature of the proposed amendment, that it will have no impact on jobs and employment opportunities.

## **SUMMARY OF ASSESSMENT OF PUBLIC COMMENT**

The New York State Department of Health (Department) received comments from healthcare professional organizations, healthcare providers, schools and the general public regarding the proposed amendments to Subpart 66-1 of Title 10 of the New York Codes, Rules and Regulations, relating to school immunization requirements.

The NYS American Academy of Pediatrics, the NYS Academy of Family Physicians, the NYS Association of County Health Officials, the American Nurses' Association, the Medical Society of the State of New York, the NYS Society of Dermatology and Dermatologic Surgery, and private individuals all expressed support of the regulations.

Additional comments and the Department's responses are summarized below.

Comment: Under section 66-1.1(j)(2) in the proposed regulation, a child is in process when “a child is obtaining serologic tests within 14 days of notification of the parent/guardian that such testing is requested.” Some commenters suggested that this language is unclear.

Response: The Department made a technical amendment to the final rule, in section 66-1.1(j)(2), to clarify that a child is “in process” if the “child has had blood drawn for a serologic test and is awaiting test results within 14 days after the blood draw.”

Comment: Under section 66-1.1(j)(4) in the proposed regulation, a child is no longer “in process” and must be excluded from school “within 14 days of the missed dose” unless otherwise exempt. Some commenters stated that this language is unclear.

Response: The Department made a technical amendment to the final rule, in section 66-1.1(j)(4), to clarify that a child is no longer in process and must be excluded from school “within 14 days after the minimum interval identified by the ACIP catch-up schedule.”

Comment: Some commenters argued that the repeal of non-medical exemptions to school immunization requirements infringes students’ and their parents’ rights to religious liberty.

Response: Non-medical exemptions to the requirements of Public Health Law (PHL) § 2164 were repealed by the enactment of Chapter 35 of the Laws of 2019. The Department respectfully disagrees that Chapter 35 of the Laws of 2019 unconstitutionally infringes religious freedom under either the United States or the New York State Constitution.

Comment: Commenters stated that the repeal of non-medical exemptions is causing financial and emotional distress.

Response: Families experiencing distress related to homeschooling may enroll their children in school provided that their children comply with PHL § 2164 and other requirements established by the New York State Education Department and any relevant school board or individual school policies.

Comment: Some commenters argue that the Department is incorrectly interpreting the ACIP schedule.

Response: The federal Centers for Disease Control and Prevention (CDC) has issued guidance stating that “[a]s a general rule, infants or children who are more than 1 month or 1 dose behind schedule should be on an accelerated schedule, which means the intervals between doses should be reduced to the minimum allowable.”

Comment: Some commenters stated that the amended requirements for medical exemptions are too strict.

Response: The definition of “[m]ay be detrimental to the child’s health” includes medical contraindications or precautions to a specific immunization consistent with ACIP guidance or other nationally recognized evidence-based standard of care. The regulations do not remove a physician’s ability to issue a medical exemption.

Comment: Some commenters asked that the Department provide additional time for children to be vaccinated before enforcing school immunization requirements.

Response: Non-medical exemptions to the requirements of PHL § 2164 were repealed by the enactment of Chapter 35 of the Laws of 2019, which went into effect immediately upon enactment of the law.

Comment: Some commenters argued that only religious exemptions to measles-containing vaccines should be repealed.

Response: The repeal of non-medical exemptions to the requirements of PHL § 2164, enacted in Chapter 35 of the Laws of 2019 applies to all school immunization requirements, not only measles immunizations.

Comment: Some commenters stated that unvaccinated children do not pose a risk to the public health and that the Department has not sufficiently documented vaccine preventable disease transmission from unvaccinated individuals to other people.

Response: An analysis of confirmed cases of measles in New York State outside of New York City found that 80% of confirmed cases occurred in children less than 18 years of age, and that 92% of the children with confirmed measles had no or unknown MMR vaccine status.

Comment: Several commenters questioned the safety of vaccines.

Response: The United States' long-standing vaccine safety system ensures vaccines are as safe as possible and that national vaccine recommendations are modified as appropriate when new vaccine effectiveness or safety data becomes available. The CDC, American Academy of Pediatrics, American Association of Family Physicians, American College of Physicians and other reliable healthcare and public health associations all agree that vaccines are a safe, effective and important preventive measure.

Comment: Some commenters questioned why children are required to be immune to types 2 or 3 poliovirus.

Response: The CDC and ACIP continue to recommend that children be immune to all three types of poliomyelitis.

Comment: One commenter noted that PHL § 2168 does not require reporting of the reasons for medical exemptions in the New York State Immunization Information System (NYSIIS).

Response: Regulations in place prior to the emergency adoption of these regulations in August 2019, already required that “[f]or individuals exempt from administration of vaccines, providers must submit patient information, including the reason for the exemption,” to NYSIIS.

Comment: Some commenters noted that the regulations only require immunizations for students but not for teachers, staff and visitors to schools nor for students aged eighteen years or older.

Response: PHL § 2164 only requires immunizations for children between the ages of two months and eighteen years entering or attending public, private or parochial child caring center, day nursery, day care agency, nursery school, kindergarten, elementary, intermediate or secondary school.

## ASSESSMENT OF PUBLIC COMMENT

The New York State Department of Health (Department) received comments from healthcare professional organizations, healthcare providers, schools and the general public regarding the proposed amendments to Subpart 66-1 of Title 10 of the New York Codes, Rules and Regulations, relating to school immunization requirements.

Comments from the NYS American Academy of Pediatrics, the NYS Academy of Family Physicians, the NYS Association of County Health Officials, the American Nurses' Association, the Medical Society of the State of New York, the NYS Society of Dermatology and Dermatologic Surgery, and private individuals, expressed support of the regulations. These comments in support are noted by the Department.

Additional comments and the Department's responses are summarized below.

Comment: Under section 66-1.1(j)(2) in the proposed regulation, a child is in process when "a child is obtaining serologic tests within 14 days of notification of the parent/guardian that such testing is requested." Some commenters suggested that it is unclear who may request the test or what timing would apply when the parent or guardian requests serologic testing without prior notification.

Response: The Department appreciates this feedback and has taken steps to provide further clarification. Specifically, the Department issued a "Frequently Asked Questions" document on October 4, 2019, located at

[https://www.health.ny.gov/prevention/immunization/schools/school\\_vaccines/docs/2019-10\\_vaccination\\_requirements\\_faq.pdf](https://www.health.ny.gov/prevention/immunization/schools/school_vaccines/docs/2019-10_vaccination_requirements_faq.pdf), which specifies that “[a] child who is obtaining serologic tests is in process within 14 days of when such testing is requested. The school may permit the child to attend school so long as the child receives a positive serologic test (for measles, mumps, rubella, varicella, or hepatitis B), or laboratory confirmation of disease (for measles, mumps, rubella, or varicella) within 14 days.” The Department made a technical amendment to the final rule, in section 66-1.1(j)(2), to clarify that a child is “in process” if the “child has had blood drawn for a serologic test and is awaiting test results within 14 days after the blood draw.”

Comment: Under section 66-1.1(j)(4) in the proposed regulation, a child is no longer “in process” and must be excluded from school “within 14 days of the missed dose” unless otherwise exempt. Some commenters stated that the proposed regulation is unclear as to when a dose has been “missed” and whether the exclusion must occur within 14 days before or after the missed dose.

Response: The Department appreciates this feedback and has taken steps to provide further clarification. The Department issued a “Frequently Asked Questions” document on October 4, 2019, located at

[https://www.health.ny.gov/prevention/immunization/schools/school\\_vaccines/docs/2019-10\\_vaccination\\_requirements\\_faq.pdf](https://www.health.ny.gov/prevention/immunization/schools/school_vaccines/docs/2019-10_vaccination_requirements_faq.pdf), which specifies that exclusion of students no longer “in process” and without a medical exemption should occur within 14 days after the minimum interval identified by the Advisory Committee on Immunization Practices (ACIP) catch-up schedule.

The Department made a technical amendment to the final rule, in section 66-1.1(j)(4), to clarify that a child is no longer in process and must be excluded from school “within 14 days after the minimum interval identified by the ACIP catch-up schedule.” For example, if the minimum interval between the first dose and the second dose is 28 days, and the child received the first dose but has not received the second dose within 42 days after the first dose, then the child must be excluded, if not otherwise exempt in accordance with section 66-1.3.

Comment: Some commenters argued that the repeal of non-medical exemptions to school immunization requirements infringes students’ and their parents’ rights to religious liberty.

Response: Non-medical exemptions to the requirements of Public Health Law (PHL) § 2164 were repealed by the enactment of Chapter 35 of the Laws of 2019. The Department respectfully disagrees that Chapter 35 of the Laws of 2019 unconstitutionally infringes religious freedom under either the United States or the New York State Constitution. No changes were made to the regulation in response to this comment.

Comment: Commenters stated that the repeal of non-medical exemptions is causing financial and emotional distress due to homeschooling or school exclusion of children who are neither completely vaccinated nor have a medical exemption to vaccination requirements.

Response: As established in PHL § 2164, children must be fully immunized with all doses in required vaccine series, in process of completing the vaccine series, or have a medical exemption to required vaccines in order to attend public, private or parochial schools in New York State. Families experiencing distress related to homeschooling may enroll their children in school provided that their children comply with PHL § 2164 and other requirements established by the

New York State Education Department and any relevant school board or individual school policies. No changes were made to the regulation in response to this comment.

Comment: Some commenters argue that the Department is incorrectly interpreting the ACIP schedule by requiring students with incomplete vaccine series to complete the series in accordance with the minimum intervals established by the ACIP, as the ACIP schedule does not require next doses in the series to be given immediately after the minimum interval elapses.

Response: PHL § 2164 requires that students who are not fully immunized with all doses in required vaccine schedules nor have medical exemptions to vaccines must have “age appropriate appointments scheduled to complete the immunization series according to the Advisory Committee on Immunization Practices Recommended Immunization Schedules for Persons Aged 0 through 18 Years.” The 2019 ACIP Recommended Child and Adolescent Immunization Schedule states that the minimum intervals indicated on Table 2 (Catch-up immunization schedule) comprise the recommended intervals for persons aged 4 months – 18 years who have started the vaccine series late or who are more than 1 month behind. The federal Centers for Disease Control and Prevention (CDC) has also issued guidance stating that “[a]s a general rule, infants or children who are more than 1 month or 1 dose behind schedule should be on an accelerated schedule, which means the intervals between doses should be reduced to the minimum allowable. Catch-up schedules for children ages 4 months through 18 years are included with each year’s recommended immunization schedule that is issued by ACIP, AAP, and American Academy of Family Physicians (AAFP).” No changes were made to the regulation in response to this comment.

Comment: Some commenters stated that the amended requirements for medical exemptions are too strict and only allow a very limited number of conditions. Medical exemptions should be at the discretion of the child's physician.

Response: Medical exemptions to school immunization requirements should only be issued for valid medical reasons. As such, the Department defined "[m]ay be detrimental to the child's health" in the regulations and required that medical exemptions must be issued on a form approved by the Department or the NYC Department of Education. The definition of "[m]ay be detrimental to the child's health" includes medical contraindications or precautions to a specific immunization consistent with ACIP guidance or other nationally recognized evidence-based standard of care. Medical exemptions must be issued by a physician licensed to practice medicine in New York State in accordance with requirements established in PHL § 2164. The regulations do not remove a physician's ability to issue a medical exemption, but they provide additional clarity to existing requirements regarding which type of medical exemptions schools may accept. No changes were made to the regulation in response to this comment.

Comment: Some commenters asked that the Department provide additional time for children to be vaccinated before enforcing school immunization requirements.

Response: Non-medical exemptions to the requirements of PHL § 2164 were repealed by the enactment of Chapter 35 of the Laws of 2019, which went into effect immediately upon enactment of the law. As such, the Department is obligated to execute and implement PHL § 2164 in accordance with the effective date established in statute. No changes were made to the regulation in response to this comment.

Comment: Some commenters argued that only religious exemptions to measles-containing vaccines should be repealed, while religious exemptions should be allowed to continue for all other vaccines.

Response: The repeal of non-medical exemptions to the requirements of PHL § 2164, enacted in Chapter 35 of the Laws of 2019 applies to all school immunization requirements, not only measles immunizations. The Department is obligated to implement and execute the law as enacted. Furthermore, other vaccine preventable diseases have the potential to cause outbreaks. School immunizations protect the public against outbreaks of diseases such as, but not limited to, meningococcal disease, mumps, and pertussis, not only measles. No changes were made to the regulation in response to this comment.

Comment: Some commenters stated that unvaccinated children do not pose a risk to the public health and that the Department has not sufficiently documented vaccine preventable disease transmission from unvaccinated individuals to other people.

Response: In October 2018 alone, the Department and Rockland County Department of Health documented transmission of measles from seven unvaccinated individuals to at least thirty-two other known persons. This rapid and widespread transmission of measles in an unvaccinated community resulted in the largest and longest outbreak of measles in the United States since 2000. From October 2018 to September 2019, 1,056 confirmed cases of measles were reported in New York State, including 407 cases in New York State outside of New York City. An analysis of confirmed cases of measles in New York State outside of New York City found that 80% of confirmed cases occurred in children less than 18 years of age, and that 92% of the

children with confirmed measles had no or unknown MMR vaccine status. No changes were made to the regulation in response to this comment.

Comment: Several commenters questioned the safety of vaccines.

Response: The United States' long-standing vaccine safety system ensures vaccines are as safe as possible and that national vaccine recommendations are modified as appropriate when new vaccine effectiveness or safety data becomes available. The CDC, American Academy of Pediatrics, American Association of Family Physicians, American College of Physicians and other reliable healthcare and public health associations all agree that vaccines are a safe, effective and important preventive measure. In addition, PHL § 2164 and these regulations authorize medical exemptions to school immunization requirements in those case where immunization may be detrimental to a child's health. No changes were made to the regulation in response to this comment.

Comment: Some commenters questioned why children are required to be immune to types 2 or 3 poliovirus, even though type 2 poliovirus was declared eradicated by the World Health Organization (WHO) in 2015 and type 3 was declared eradicated by the WHO in October 2019.

Response: On January 13, 2017, the CDC published updated guidance for assessment of poliovirus vaccination status and vaccination of children who have received poliovirus vaccine outside the United States. Although wild poliovirus type 2 (WPV2) was declared eradicated in September 2015, type 2 vaccine-derived polioviruses continued to be detected in several countries of the world even after WPV2 was declared eradicated. As such, the CDC and ACIP continued to recommend that children be immune to all three types of poliomyelitis, and that

children with evidence of immunity to only 1 or 2 strains receive a complete poliomyelitis vaccine series against all 3 strains. In the same guidance document, the CDC stated that “serologic testing is no longer recommended to assess immunity.” As such, the acceptable evidence of immunity to poliomyelitis for children entering or attending schools was amended to no longer allow serologic tests to assess immunity to poliomyelitis performed on or after September 1, 2019 to be accepted in place of poliomyelitis vaccination. Serologic tests performed prior to September 1, 2019 may continue to be accepted only if they are positive for all three serotypes of poliomyelitis. This change was made to reflect current CDC and ACIP recommendations. Although wild poliovirus type 3 was declared eradicated in October 2019, the ACIP has not issued any changes to its recommendation that U.S. children be immune to all three types. No changes were made to the regulation in response to this comment.

Comment: One commenter noted that PHL § 2168 does not require reporting of the reasons for medical exemptions in the New York State Immunization Information System (NYSIIS). Therefore, this commenter asked that subparagraph (ii) of paragraph (4) of subdivision (c) of section 66-1.2 be revised to only require that NYSIIS shows that the child has a medical exemption.

Response: Regulations in place prior to the emergency adoption of these regulations in August 2019, already required that “[f]or individuals exempt from administration of vaccines, providers must submit patient information, including the reason for the exemption,” to NYSIIS. These regulations did not introduce this requirement but simply sought to clarify the definition of medical exemption, consistent with that used in subdivision (l) of section 66-1.1. NYSIIS is a lifelong immunization record; as such, the reason why an immunization may be detrimental to a

child's health is necessary information for the child's future healthcare providers. No changes were made to the regulation in response to this comment. However, the Department made a technical amendment to the final rule, to change an incorrect reference, in subparagraph (ii) of paragraph (4) of subdivision (c) of section 66-1.2. The words "this section" were changed to "section 66-1.1 of this Subpart."

Comment: Some commenters noted that the regulations only require immunizations for students but not for teachers, staff and visitors to schools nor for students aged eighteen years or older. These other populations could also introduce vaccine-preventable diseases into schools.

Response: PHL § 2164 only requires immunizations for children between the ages of two months and eighteen years entering or attending public, private or parochial child caring center, day nursery, day care agency, nursery school, kindergarten, elementary, intermediate or secondary school. No changes were made to the regulation in response to this comment.